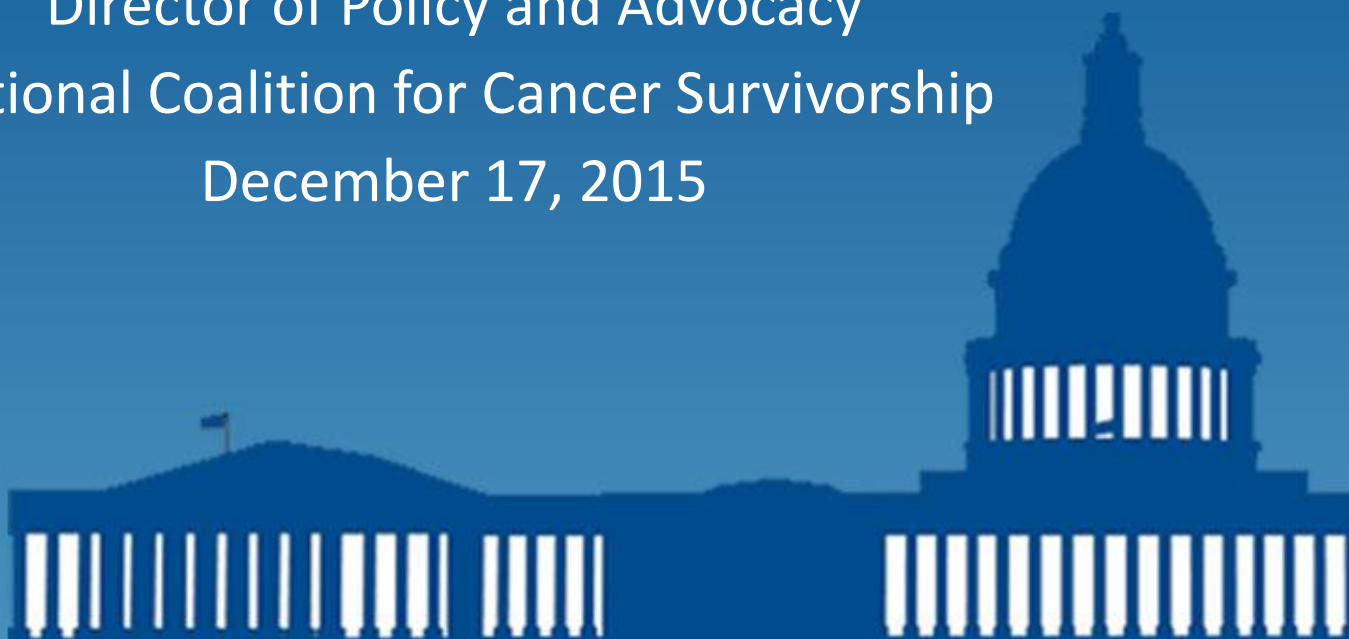


PDUFA Stakeholder Meeting

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About NCCS

- Our mission is to advocate for **quality cancer care** for all people touched by cancer.
- We represent **cancer survivors** in **public policy efforts** to improve cancer treatments and to enhance access to quality cancer care.
- **Our goal** is to foster a cancer care system that is evidence-based, quality-driven, **patient-focused**, and affordable and accessible to all.
- We believe in **shared decision-making**.
- We champion **cancer care planning**, at diagnosis and at major transition points during treatment and survivorship.

Making Treatment Decisions



Complete this worksheet and use it to help you prepare for your doctor's visit and discuss your wishes with your physician and your family. 🗨️



MY HOPES ▶ Through cancer treatment, I hope for [cure, control, comfort] ▼

MILESTONES AND GOALS ▶ Milestones and goals that are important to me (examples: graduations, weddings, retirement, trips, accomplishments) ▼

QUALITY OF LIFE ▶ During treatment, I want to be able to ▼

When I finish my cancer treatments, I want to be able to... ▼

SIDE EFFECTS ▶ Side effects I am afraid of during treatment ▼

Side effects I am afraid of during treatment ▼

CONCERNS ▶ Other concerns I have about my cancer and treatment (examples: body image, fertility, emotional health, sexuality):

SUPPORT ▶ Do my family members agree with and support my wishes?
▶ Do I need help communicating my wishes?

Support I need from my family and caregivers — day of treatment, managing side effects, etc.

- What **information do I need** to help me make a decision about treatment?
- What **information do you use** to make treatment recommendations for me?
- What are your **realistic goals** for my treatment?
- What are the chances that I can be **cured**?
- What are my chances of a **long-term response** with good **quality of life**?
- Are there **clinical trials** available to me?
- How will I feel during **treatment**? Will I be able to **work**? Take care of my **family**? **Travel**? Be around young children?
- What help will I need in **managing the side effects** of treatment? When and for how long?
- Should I consider a **second opinion** regarding my diagnosis and treatment? Are there **different approaches** to treating my kind of cancer?

ESSENTIAL QUESTIONS TO ASK YOUR DOCTOR



canceradvocacy.org/careplans

PDUFA Opportunities

- PDUFA can enhance the scientific expertise, processes, and tools that FDA uses to regulate increasingly complex medical problems and public health.
 - To continue to improve the drug-approval process and to make it more efficient
 - To continue to implement advances in science

PDUFA Opportunities for Oncology

- To advance the understanding of and appropriate use of adaptive clinical trials
- To advance the science of conducting clinical trials for combination therapy
- To continue to advance the work to date in biomarkers

Patients at the Heart of Drug Development

- Patients' experiences matter.
- Patient-reported outcomes (PROs), properly collected and analyzed, can be immensely helpful to patients in shared decision-making.
- There can be tremendous benefit to including PROs, properly collected and analyzed, in the drug-development process.
 - Patients may learn more about what to expect from the drug, including possible side effects.

FDA Questions on PROs

- How can the patient-reported evidence be integrated and evaluated?
- How could individual differences in patient experience of benefit versus harm be considered?

Post-Market Activities

- The need to have effective tools for post-market activities related to oncology drugs